

REMARKS

On February 28, 2011, Applicants filed a Request for Continued Examination. The Office has on March 7, 2011, mailed a Notice of Improper Request for Continued Examination, indicating that the RCE filed on February 29, 2011 was improper in failing to be accompanied by any "submission" pursuant to 37 CFR 1.114.

To the contrary, Applicants included with the RCE a statement of substance of interview and a request for suspension of action in order to provide further time for preparing experimental data for submission in a Rule 132 Declaration (see the front page of the RCE filed February 28, 2011). Applicants did inadvertently fail to check the boxes on the RCE form indicating that a response in the nature of "other" and indicating the Statement of Substance of Interview had been filed.

In order to comply with the Notice, Applicants provide here additional remarks in support of the RCE.

Applicants have previously argued that there is a plain point of distinction of the invention over the prior art in that in the present invention, the gangcyclovir is made into a neutral to acidic solution prior to packaging. This feature is recited in the independent claims 44 ("free acid form, free from alkaline residues") and 54 ("pH ranging from 3.0 to 6.9") but is not disclosed or suggested in the combination of references cited by the Examiner. Applicants have accordingly argued that the Examiner fails to establish *prima facie* obviousness of the present invention and the instant rejection should be withdrawn.

Applicants have also previously provided evidence of results obtained by the invention that are not expected by one of ordinary skill in the art who reads Smith '475 in view of Harris '258 and Mueller '776, and serves as objective evidence of unobviousness of the present invention. Specifically, Applicants have provided the Declaration of Mr. H. Perillo that establishes that the state of the art at the time the invention was made was such that solutions of gangcyclovir for administration were of high pH, and that they were unstable in the absence of refrigeration. Mr. Perillo's testimony establishes that, in contrast, by eliminating alkaline

residues from the crystalline gancyclovir that is dissolved for administration, the stability of the solution of gancyclovir is greatly and unexpectedly enhanced.

This evidence was not found persuasive by the Examiner, and therefore an interview with the Examiner was conducted December 9, 2010. In that interview, the evidence of unobviousness in the record was discussed. The Examiner requested a direct comparison of the present invention with a commercially available preparation of gancyclovir. Applicants presented in the RCE filed on February 28, 2011 a statement of substance of interview describing the discussion with the Examiner in an attempt to move the prosecution forward, and a request for suspension of action in this application in order to provide the time for performing such direct comparative experiment and preparation of the results in Declaration form for presentation in the present application.

Confirmation that the Statement of Substance of Interview filed February 28, 2011 is a sufficient "response" to support the RCE filed February 28, 2011 and that present application remains pending, and acknowledgment of the suspension of action requested February 28, 2011 are requested.

Should there be any outstanding matters that need to be solved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in the connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.R.F. §§1.16 or 1.14; particularly, extension of time fees.

Dated: March 7, 2011

Respectfully submitted,

By 
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Attachment: copy of Notice of Improper Request for RCE